REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133. The outstanding office action is non-final because new rejections not necessitated by amendment were added.

Status of the Claims

Pending claims

Claims 1 to 29 are pending and under consideration.

Claims added and deleted in the instant amendment

Claims 30 to 36 are added, and claims 11 to 13 are deleted, without prejudice or disclaimer. Thus, after entry of the instant amendment, claims 1 to 10 and 14 to 36, will be pending and under consideration.

Outstanding Rejections

Claims 1, 2, 11, 12, 14, 17, 20 to 25, 27, and 28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Strehlow *et al.* (J. Clin. Invest. (1999) 103(8):1179-90).

Claims 1, 2, 11, 12, and 14 to 28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Budde *et al.* (Oncogene (1998) 19:1119-24).

Claims 1-3, 11, 12, 14, 19 to 25, and 27 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Dennery *et al.* (J. Biol. Chem. (1997) 272(23):14937-42).

Claims 1, 2, 5, 19 to 25, and 27 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tovar *et al.* (Nucl. Acids Res. (1996) 24(15):2942-49).

Claims 1, 2, 5, 10, 12, and 19 to 27 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Bigbee *et al.* (Brain Research (2000) 861:354-62).

Claims 1, 2, 10, 12, 14, 19 to 25, 27, and 29 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Lightner *et al.* (U.S. Patent No. 6,372,965).

Claims 1 to 4, 11, 12, and 19 to 28 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Sedivy *et al.* (U.S. 2004/0018570).

Claims 1 and 6 to 8 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Strehlow, Budde, Dennery, Bigbee, or Sedivy, in view of Yee *et al.* (U.S. Patent No. 5,817,491).

Claims 12 and 13 were rejected under 35 U.S.C. §112, second paragraph.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. For example, support for methods comprising high throughput detecting, e.g., comprising use of computerized or robot implemented systems, or libraries of lentiviral vectors and cells transduced by the lentiviral vectors, or libraries of lentiviral vectors and cells transduced by the lentiviral vectors in a multiplicity of compartments, or machine implemented microarray or macroarray technology, can be found, inter alia, on page 9, first through fourth paragraphs, of the specification. Support for methods wherein said overexpressing of a gene sequence by use of a conditionally replicating pseudotyped lentiviral vector can be found, inter alia, on page 6, last paragraph, of the specification.

Accordingly, no new matter is added by the instant amendment.

Information Disclosure Statement

Two references cited in the Information Disclosure Statement (IDS) submitted September 05, 2003, were not considered (and thus initialed by the Examiner) because the Office noted that they "are not publicly available."

However, reference 1 (on sheet 1 of 1, in the 09/05/03 IDS), or USSN 09/653,088, issued on September 30, 2003, as USPN 6,627,442.

Reference 2 (on sheet 1 of 1, in the 09/05/03 IDS), or USSN 09/667,893, is the priority document for the international application PCT/US01/29976, that published as WO 02/24897, on March 28, 2002.

Both USPN 6,627,442, and WO 02/24897, are cited and submitted in the supplementary IDS attached herein.

Restriction Requirement

Applicants thank the Examiner for considering their statements and request for reconsideration of the restriction requirement and rejoining all pending claims.

Issues under 35 U.S.C. §102

Claims 1, 2, 11, 12, 14, 17, 20 to 25, 27, and 28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Strehlow *et al.* (J. Clin. Invest. (1999) 103(8):1179-90) (hereinafter "Strehlow").

Claims 1, 2, 11, 12, and 14-28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Budde *et al.* (Oncogene (1998) 19:1119-24) (hereinafter "Budde").

Claims 1 to 3, 11, 12, 14, 19 to 25, and 27 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Dennery *et al.* (J. Biol. Chem. (1997) 272(23):14937-42) (hereinafter "Dennery").

Claims 1, 2, 5, 19 to 25, and 27 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tovar *et al.* (Nucl. Acids Res. (1996) 24(15):2942-49) (hereinafter "Tovar").

Claims 1, 2, 5, 10, 12, and 19 to 27 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Bigbee *et al.* (Brain Research (2000) 861:354-62) (hereinafter "Bigbee") .

Claims 1, 2, 10, 12, 14, 19 to 25, 27, and 29 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Lightner *et al.* (U.S. Patent No. 6,372,965) (hereinafter "Lightner").

Claims 1 to 4, 11, 12, and 19 to 28 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Sedivy *et al.* (U.S. 2004/0018570) (hereinafter "Sedivy").

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. In re Paulson, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994)(citing In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131; pg 2100-73, 8th ed., Rev. 2, May 2004.

Claim 1 as amended is directed to high throughput methods of identifying a function of a polypeptide-encoding sequence of interest endogenously expressed by a cell type comprising, inter alia, use of pseudotyped lentiviral vectors for expressing a least a part of a polypeptide-encoding sequence (e.g., a gene) or a complementary sequence thereof, wherein vectors are designed to overexpress and/or inhibit or terminate expression of the sequence, and a high throughput detecting step comprising detecting at least one change in one or more endogenous cellular factors in cell populations and comparing the effect on the cells of overexpression of the polypeptide-encoding sequence with the effect on the cells of inhibition or termination of expression of the polypeptide-encoding sequence.

Claim 21 as amended is directed to high throughput methods of identifying a function of a gene sequence of interest in a cell heterologous to the cellular source of the gene comprising, inter alia, use of pseudotyped lentiviral vectors for expressing a least a part of a polypeptide-encoding sequence (e.g., a gene) or a complementary sequence thereof, wherein vectors are designed to overexpress and/or inhibit or terminate expression of the sequence, and a high throughput detecting step comprising detecting at least one change in one or more cellular factors in cell populations and comparing the effect on the cells of overexpression of the gene sequence with the effect on the cells of inhibition or termination of expression of the gene sequence.

Claim 22 as amended is directed to high throughput methods of detecting a change in one or more cellular factors in a cell due to the overexpression or inhibition of a gene sequence of interest in the cell comprising, inter alia, use of pseudotyped lentiviral vectors for expressing a least a part of a polypeptide-encoding sequence (e.g., a gene) or a complementary sequence thereof, wherein vectors are designed to overexpress and/or inhibit or terminate expression of the sequence, and a high throughput detecting step comprising detecting at least one change in one or more cellular factors in cell populations by comparing the effect on the cells of overexpression of the gene sequence with the effect on the cell of inhibition or termination of expression of the gene sequence.

Additionally, in all of the amended claimed methods, the lentiviral vectors only express the polypeptide-encoding sequence of interest or complementary sequence thereof; thus, these lentiviral vectors do not express any exogenous protein.

None of the cited references Strehlow, Budde, Dennery, Tovar, Bigbee, or Sedivy teaches use of pseudotyped lentiviral vectors that lack any exogenous protein expression in methods comprising high throughput detecting of at least one change in one or more cellular factors (e.g., endogenous cellular factors) in a cell population.

Accordingly, the rejection of claims, as noted above, under section 102 can be properly withdrawn.

Issues under 35 U.S.C. §103(a)

Claims 1 and 6 to 8 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Strehlow, Budde, Dennery, Bigbee, or Sedivy, in view of Yee *et al.*, U.S. Patent No. 5,817,491, issued October 06, 1998, filed December 22, 1994 (hereinafter "Yee").

The Patent Office notes that the cited references Strehlow, Budde, Dennery, Bigbee and Sedivy are defective in that they do not teach use of pseudotyped lentiviral vectors to overexpress or inhibit expression of a gene sequence (see, e.g., page 8, third paragraph, of the OA).

However, Applicants respectfully aver that the cited references Strehlow, Budde, Dennery, Bigbee and Sedivy are further defective in that they do not teach or suggest use of pseudotyped lentiviral vectors that lack any exogenous protein expression in methods (e.g., the amended claimed methods) comprising overexpression or inhibition of a gene sequence in a cell population, followed by high throughput detection of at least one change in one or more cellular factors (e.g., endogenous cellular factors) in the cell population.

Yee is cited to cure the defect(s) in Strehlow, Budde, Dennery, Bigbee and Sedivy. However, Yee cannot cure the defect(s) in the cited referenced because, inter alia, Yee does not teach or suggest use of pseudotyped lentiviral vectors that lack any exogenous protein expression in methods comprising overexpression or inhibition of a gene sequence in a cell population, followed by high throughput detection of at least one change in one or more cellular factors (e.g., endogenous cellular factors) in the cell population.

None of the cited references in any combination teach or suggest the (amended) claimed invention; only the (amended) claimed methods comprise, inter alia, use of lentiviral vectors that lack any exogenous protein expression in high throughput detection assays. The present invention's use of such lentiviral vectors in a high throughput detection assay provides for the first time the claimed combination of an efficient and stable expression system in high throughput detection of changes in cellular factors in a cell population.

Accordingly, because Strehlow, Budde, Dennery, Bigbee, or Sedivy, in view of Yee does not teach or suggest the (amended) claimed invention, the rejection under section 103 can be properly withdrawn.

Issues under 35 U.S.C. §112, second paragraph

Claims 12 and 13 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The instant amendment addresses this issue.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, second paragraph, 35 U.S.C. §102 and 35 U.S.C. §103(a). In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 397272000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 720 5133.

Dated: December 14, 2005

Respectfully submitted,

By _____

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